



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

MAR 16 2004

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Jonathan W. Emord, Esq.  
Emord and Associates, P.C.  
5282 Lyngate Court  
Burke, VA 22015

RE: Qualified Health Claim Petition – Calcium and Menstrual Disorders (Docket  
No. 2004Q-0099)

Dear Mr. Emord:

This letter acknowledges receipt on March 3, 2004 by the Food and Drug Administration (FDA) of your letter dated March 2, 2004 regarding the various calcium health claim petitions you submitted on November 25, 2003 on behalf of Marine Bio USA, Inc. We understand that the petitioner has elected to have their health claim petitions reviewed under the new process for qualified health claims rather than under the standard health claim review process described in Section 403(r)(5)(D) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 343(r)(5)(D)). We will follow the interim procedures for qualified health claims described in the FDA publication entitled “Consumer Health Information for Better Nutrition Initiative” Task Force Final Report (<http://www.cfsan.fda.gov/~dms/nuttfoc.html>).

Accordingly, today we are filing your qualified health claim petition about the relationship between calcium and (1) cyclic severe depression associated with the menstrual cycle, (2) premenstrual dysphoric disorder, (3) the onset of symptoms of premenstrual dysphoric disorder, (4) abnormal menstrual cycles, and (5) polycystic ovary syndrome. The petition is posted on Dockets web page (<http://www.fda.gov/ohrms/dockets/dockets/dockets.htm>) and we are requesting comment on it for 60 days. Interested persons may submit comments until May 17, 2004. Within 225 days of the filing date we will notify you of our final decision regarding the requested qualified health claim. We have calculated that date to be October 27, 2004.

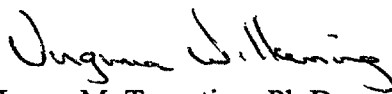
2004Q-0099

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Please feel free to contact Dr. Tomoko Shimakawa at 301-436-1450 if you have any questions concerning this petition.

Sincerely yours,

  
for Laura M. Tarantino, Ph.D.  
Acting Director  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition